REMARKS

Applicants gratefully acknowledge the Examiner's indication that claims 59, 62, and 63 are allowable. Applicants also thank the Examiner for the recent telephonic interview conducted on October 27, 2004, during which the outstanding rejections of record were discussed, as reflected in the following remarks. In addition, Applicants agreed to make the following amendments.

Amendments to the specification

A revised sequence listing is being submitted herewith. The revised sequence listing provides SEQ ID NOs (SEQ ID NOs:9-17) for the germline sequences (V_H 3-30.3, V_K L18, V_K A27, D 6-13, JH4b, JK3, D 7-27, and JH3b) described in the specification (*e.g.*, at page 7, lines 10-16) and recited in pending claims 64-66. As described in detail below, these sequences were well known in the art and publicly available, for example, in the VBASE gene database at the time the present application was filed. Accordingly, no new matter has been added.

The specification has been further amended to insert the corresponding sequence identifiers for the nucleotide and amino acid sequences referred to in the brief description of the drawings (page 7). No new matter has been added.

Amendments to the claims

Claims 52-100 were pending.

Claims 52-58, 70, 72-84, 86, 87, 90, 92-96, and 100 have been canceled without prejudice. Accordingly, claims 59-69, 71, 85, 88, 89, 91, and 97-99 are currently pending.

Claims 59-61, 64-69, 71, 85, 88, 91, 97, and 99 have been amended.

Specifically, claims 59, 64-69, 71, 85, 88, 91, 97, and 99 have been amended to specify an "antibody, or antigen binding portion thereof," in order to provide proper antecedent basis and consistency among all of the pending claims. Claims 67-69, 71, 85, 88, 91, 97, and 99 have been further amended to provide proper dependency.

Claims 64-66 have been amended to provide sequence identifiers for the human germline (heavy and light chain) genes, V_H 3-30.3, V_K L18, and V_K A27. As previously

discussed, these human gene sequences were publicly available at the filing data of the present application and, thus, do not constitute new matter.

Claim 97 has been further amended to correct a typographical error. Support for this amendment can be found throughout the specification as originally filed.

The foregoing amendments should in no way be construed as acquiescence to any of the Examiner's rejections and were made solely to expedite prosecution. Applicants reserve the right to pursue the claims as originally filed in this or a separate application(s). No new matter has been added.

Restriction Requirement

Applicants gratefully acknowledge the Examiner's consideration of their arguments made in support of the traversal of the Restriction Requirement dated April 20, 2004. Applicants thank the Examiner for extending the prior art search to include both antibody species encompassed by the invention of elected Group I.

Applicants further note that the nonelected process claims (claims 71, 91, and 97-99) have been amended to depend from the elected product claims (claims 59, 60 and 61), such that they include all of the limitations of the elected product claims. Accordingly, Applicants understand that, once the product claims are found allowable, the nonelected process claims will be rejoined (MPEP 821.04).

37 CFR §1.821(d)

The specification is objected to for lacking SEQ ID NOs in the brief description of the drawings (page 7). Accordingly, Applicants have amended the specification to provide the appropriate SEQ ID NOs and, thus, the objection is now moot.

35 U.S.C. §112, Second Paragraph

Claims 64-69, 85, 88 and 89 are rejected as being indefinite. Specifically, the Examiner asserts that claims 64-66 are indefinite based on reference to the V_H 3-30.3, V_K L18, and V_K A27 germline genes "because the characteristics of these genes are not known." The Examiner further states that the use of such terms

> as the sole means of identifying the claimed gene without providing SEQ ID NOs for said genes renders the claim indefinite because "V_H 3-30.3, V_K L18 or V_K A27" is merely a laboratory designation which does not

clearly define the claimed product, since different laboratories may use the same laboratory designation to define completely distinct products.

Applicants respectfully traverse this rejection. The nomenclature and characteristics (including sequences) of the V_H 3-30.3, V_K L18, and V_K A27 germline designations referred to in claims 64-66 were well known in the art at the time the present application was filed. Indeed, the sequences for these genes were publicly available, for example, in the VBASE database (http://www.mrc-cpe.cam.ac.uk/). Therefore, reference to such germline nomenclature is not an arbitrary designation as asserted by the Examiner.

Notwithstanding, Applicants have amended the sequence listing to include the sequences corresponding to the human germline genes referenced in the specification and encompassed by the claims. Applicants have also amended the specification and claims 64-66 to include the corresponding SEQ ID NOs. Accordingly, the rejection should now be moot.

Claims 67-69, 85 and 88 are further rejected as being dependent on canceled claim 1. In response, claims 67-69, 85 and 88 have been amended to provide proper dependency. Therefore, this rejection is now moot.

35 U.S.C. §112, First Paragraph

Claims 52-58, 60, 61, 64-69, 85, 88, and 89 are rejected as not being enabled by the current specification. However, the Examiner acknowledges that the current specification is enabling for an isolated human monoclonal antibody having heavy and light chain variable regions comprising CDR1, CDR2, and CDR3 sequences as defined by heavy chain amino acid residues 30-35, 50-66, and 99-108 of SEQ ID NO:2 and light chain amino acid residues 24-34, 50-56, and 89-97 of SEQ ID NO:4, as well as heavy chain amino acid residues 31-35, 50-66, and 99-108 of SEQ ID NO:6 and light chain amino acid residues 24-35, 51-57, and 90-99 of SEQ ID NO:8. The Examiner also acknowledges that the current specification is enabling for an isolated human monoclonal antibody having heavy and light chain variable regions comprising the full length variable regions defined by SEQ ID NOs 6 and 8 or SEQ ID NOs 2 and 4.

Applicants respectfully traverse this rejection. However, to expedite prosecution, claims 52-58 have been canceled and the remaining claims have been amended to specify

the CDR1, CDR2, and CDR3 sequences, or complete variable region sequences, acknowledged to be fully enabled. Accordingly, this rejection is now moot.

35 U.S.C. §112, First Paragraph

Claims 52-58, 60, 61, 64-69, 85, 88, and 89 are rejected as failing to comply with the written description requirement. However, the Examiner acknowledges that Applicants are in possession of an isolated human monoclonal antibody having heavy and light chain variable regions comprising CDR1, CDR2, and CDR3 sequences as defined by heavy chain amino acid residues 30-35, 50-66, and 99-108 of SEQ ID NO:2 and light chain amino acid residues 24-34, 50-56, and 89-97 of SEQ ID NO:4, as well as heavy chain amino acid residues 31-35, 50-66, and 99-108 of SEQ ID NO:6 and light chain amino acid residues 24-35, 51-57, and 90-99 of SEQ ID NO:8. The Examiner also acknowledges that Applicants are in possession of an isolated human monoclonal antibody having heavy and light chain variable regions comprising the full length variable regions defined by SEQ ID NOs 6 and 8 or SEQ ID NOs 2 and 4.

Applicants respectfully traverse this rejection. However, to expedite prosecution, claims 52-58 have been canceled and the remaining claims have been amended to specify the CDR1, CDR2, and CDR3 sequences, or complete variable region sequences, acknowledged to comply with the written description requirement. Accordingly, this rejection is now moot.

35 U.S.C. §102(e)

Claims 52-55, 67-69, 85, 88, and 89 are rejected as lacking novelty over WO 01/09186 or U.S. Patent No. 6,018,031.

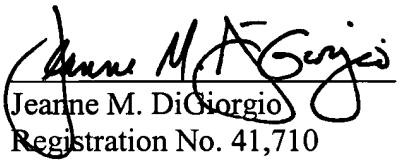
Applicants respectfully traverse this rejection. However, to expedite prosecution, claims 52-55 have been canceled and the remaining claims have been amended to depend from claims 59, 60 or 61 which are not the subject of this rejection. Accordingly, the rejection is now moot.

CONCLUSION

In view of the foregoing, allowance of the instant application with all pending claims is respectfully solicited. If a telephone conversation with Applicants' attorney would help expedite the prosecution of the above-identified application, the Examiner is urged to call Applicants' attorney at (617) 227-7400.

Respectfully submitted,

LAHIVE & COCKFIELD, LLP



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